

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for use of EXOGEN ultrasound bone healing system

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

1. Background

EA Title	Policy for use of EXOGEN ultrasound bone healing system		
EA Author	David King	Team	
Date Started	16/7/2019	Date Completed	16/7/2019
EA Version	1	Reviewed by E&D	

What are the intended outcomes of this work? Include outline of objectives and function aims

Fracture

Following immediate management of a presenting fracture through casting, traction or surgical intervention, patients receive regular follow-up to determine progression of healing. In children and adolescents healing rates in the order of 99% are usual, whilst in adults this is around 80% depending on the bone involved.

Healing of fractures varies according to the nature of the fracture and affected bone, host factors including age, co-morbidities and lifestyle factors and other issues such as surgical aspects and infection. The definition of non-union therefore can vary according to these parameters. It is usual practice to consider non-union from around 6 months following fracture; at this stage re-intervention is considered.

Long bone fractures are usually treated immediately by closed or open reduction (realignment of the bone ends, which can involve surgery). The affected limb is immobilised using a cast or by internal or external fixation. X-rays are used to verify alignment of the bone. Progress towards fracture healing is usually assessed by X-ray demonstration of bridging of the gap between the fractured bone ends with new bone cortex.

Patients with delayed fracture healing at 3 months do not usually have surgery at this time unless the fracture is complex (for example, an unstable or misaligned fracture or an inter-fragment gap of more than 10 mm). Surgery may take place between 3 and 9 months after fracture, but clinical practice varies and decisions about the timing of surgery are made on an individual patient basis. If surgery is considered necessary, it usually involves internal or external fixation and bone grafting (with harvesting from the patient's iliac crest).

Exogen Ultrasound Bone Healing System

The EXOGEN ultrasound bone healing system, delivers low-intensity pulsed ultrasound waves with the aim of stimulating bone healing. It is thought that healing is promoted by stimulating the production of growth factors and proteins that increase the removal of old bone, increase the production of new bone and increase the rate at which fibrous matrix at a fracture site is converted to mineralised bone. Long bone fractures are suitable for treatment if the fracture is stable and well-aligned. EXOGEN

is not indicated for use in fractures of the skull or vertebrae, or in children or adolescents because of their skeletal immaturity.

The EXOGEN device consists of a main operating unit with a permanently connected transducer and a separate fixture strap. The strap is placed around the fractured bone, coupling gel is applied to the transducer head (to aid conduction of ultrasound) and the transducer is secured directly over the fracture site by a fixture on the strap. The ultrasound signal emitted by the device is derived from a combination of defined electrical signal parameters and the proprietary transducer design, which generate an acoustic wave pattern specific to EXOGEN. If the patient's limb is immobilised in a cast, then a hole is cut in the cast to allow access of the transducer to the skin. The device is programmed to deliver ultrasound in 20-minute sessions and these are self-administered by the patient each day. It is intended to be used in the patient's home.

Evidence Review

The evidence reviewed was mixed, whilst NICE supported this treatment intervention in certain clinical circumstances, there was acknowledgement from the NICE Committee (MTG12) that for long bone fractures with delayed healing the Committee considered that the clinical evidence was more limited. In addition, there were significant uncertainties about the rate at which healing progresses between 3 and 9 months after fracture, both with and without EXOGEN, and about whether or not surgery would be required if EXOGEN was not used. These and other considerations influenced the Committee's views about the most appropriate assumptions for cost modelling: the model considered to be most appropriate estimated that EXOGEN treatment would be more costly than current management. The Committee therefore judged that the case for adoption of EXOGEN to treat long bone fractures with delayed healing was not supported by the current evidence.

Therefore, due to the lack of consistent evidence and in light of the uncertain cost benefits of this treatment in preventing surgery, exogen bone healing will not be routinely commissioned.

N.B. It is understood that NICE are due to published revised guidelines (MTG12 - exogen bone healing system), which if published in time, will be taken into consideration by the committee as part of the public engagement in Sept – October 2019.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Eligibility Criteria

The use of Exogen ultrasound bone healing system is Not Routinely Commissioned due to a lack of robust clinical evidence to support this intervention.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Activity data 2018/19

Number of Procedures	BSOL	Sandwell
	AS this is a piece of equipment rather than a procedure activity data is not available.	

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
<p>Guidance</p> <ol style="list-style-type: none"> 1. NICE. EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. Medical technologies guidance [MTG12] Published date: January 2013 2. Medical Services Advisory Committee. 2001. Low intensity ultrasound treatment for acceleration of bone fracture healing – Exogen™ bone growth stimulator. Australian Systematic Review. http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?AccessionNumber=3 3. Banken, R. (2004) Low-intensity ultrasound (Exogen™) for the treatment of fractures. Canadian Systematic Review) - http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?AccessionNumber=32004000158 Leighton, R.; Watson, J.T. Giannoudis, P., Papakostidis, C. Harrison, A. & Steen, R. 2017. Healing of fracture nonunions treated with low-intensity pulsed ultrasound (LIPUS): A systematic review and meta-analysis. <i>Injury</i>. 2017 		

[Jul;48\(7\):1339-1347. doi: 10.1016/j.injury.2017.05.016. Epub 2017 May](#)

4. [Bahram Biglari](#), [Timur Mert Yildirim](#), [Tyler Swing](#), [Thomas Bruckner](#), [Wolfgang Danner](#), and [Arash Moghaddam](#) (2016) Failed treatment of long bone nonunions with low intensity pulsed ultrasound [Arch Orthop Trauma Surg](#). 2016; 136: 1121–1134.
5. Ibrahim, N & Mangwani, Jitendra & Natarajan, R & Mahadevan, Dev & Chauhan, Ishant & Groom, W & Rudd, James. (2015). An internal audit on EXOGEN use in the East Midlands. *International Journal of Surgery*. 23. S86. 10.1016/j.ijssu.2015.07.390.
6. Leonidou, A. (2014) Use of the EXOGEN ultrasound bone healing system for delayed and non-unions (Maidstone and Tunbridge Wells NHS Trust) <https://www.nice.org.uk/sharedlearning/use-of-the-exogen-ultrasound-bone-healing-system-for-delayed-and-non-unions>
7. Use of the exogen ultrasound system to promoting bone healing in established non-union (2016) - [International Journal of Surgery \(London, England\)](#) 36(1):S110 · November 2

[1] NICE Guidance published January 2013 and under review as of August 2018 - <https://www.nice.org.uk/guidance/mtg12>

[2] Low-intensity ultrasound (Exogen (TM)) for the treatment of fractures (2004 Canadian Systematic Review) - <http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?AccessionNumber=32004000158>

[3] Healing of fracture nonunions treated with low-intensity pulsed ultrasound (LIPUS): A systematic review and meta-analysis (2017) - <https://www.sciencedirect.com/science/article/pii/S0020138317303418>

[4] Failed treatment of long bone nonunions with low intensity pulsed ultrasound (2016) - <https://link-springer-com.ezproxye.bham.ac.uk/article/10.1007%2Fs00402-016-2501-1>

[5] An internal audit on EXOGEN use in the East Midlands (2015) - <https://www.sciencedirect-com.ezproxye.bham.ac.uk/science/article/pii/S1743919115007566>

[6] An internal audit on EXOGEN use in the East Midlands (2015) - <https://www.sciencedirect-com.ezproxye.bham.ac.uk/science/article/pii/S1743919115007566>

com.ezproxye.bham.ac.uk/science/article/pii/S1743919115007566

[7] Use of the EXOGEN ultrasound bone healing system for delayed and non-unions (2014 Maidstone and Tunbridge Wells NHS Trust) - <https://www.nice.org.uk/sharedlearning/use-of-the-exogen-ultrasound-bone-healing-system-for-delayed-and-non-unions>

[8] Healing of fracture nonunions treated with low-intensity pulsed ultrasound (LIPUS): A systematic review and meta-analysis (2017) - <https://www-sciencedirect-com.ezproxye.bham.ac.uk/science/article/pii/S0020138317303418>

[9] Use of the exogen ultrasound system to promoting bone healing in established non-union (2016) - <https://www-sciencedirect-com.ezproxye.bham.ac.uk/science/article/pii/S1743919116307099>

[10] Griffin XL, Costa ML, Parsons N, et al. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. Cochrane Database Syst Rev. 2011;(4):CD008471. <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008471.pub2/full>

[11] Griffin XL, Parsons N, Costa ML, et al. Ultrasound and shockwave therapy for acute fractures in adults. Cochrane Database Syst Rev. 2014;(6):CD008579. <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008579.pub3/full>

[12] Rockwood CA Jr, Green DP, Bucholz RW, et al. Rockwood and Green's fractures in adults. Vol 1, 4th ed. Philadelphia, PA: Lippincott-Raven; 1996.

[13] Singer BR, McLauchlan GJ, Robinson CM, et al. Epidemiology of fractures in 15,000 adults: the influence of age and gender. J Bone Joint Surg Br. 1998;80:243-248. <https://online.boneandjoint.org.uk/doi/abs/10.1302/0301-620X.80B2.0800243>

[14] Mahabier KC, Vogels LM, Punt BJ, et al. Humeral shaft fractures: retrospective results of non-operative and operative treatment of 186 patients. Injury. 2013;44:427-430. <https://www.ncbi.nlm.nih.gov/pubmed/22938959?tool=bestpractice.com>

<p>[15] Busse JW, Bhandari M, Einhorn TA, et al. TRUST Investigators writing group. Re-evaluation of low intensity pulsed ultrasound in treatment of tibial fractures (TRUST): randomized clinical trial. BMJ2016;355:i5351 https://www.ncbi.nlm.nih.gov/pubmed/?term=27797787</p> <p>[16] Scott G, King JB. A prospective, double-blind trial of electrical capacitive coupling in the treatment of non-union of long bones. Journal of Bone and Joint Surgery - American volume 1994;76(6):820-6. [PUBMED: 8200888] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008471.pub2/full</p> <p>[17] The relative incidence of fracture non-union in the Scottish population (5.17 million): a 5-year epidemiological study, Mills LA, Simpson AHRW, BMJ Open 2013;3: e002276. doi:10.1136/bmjopen-2012-002276 https://bmjopen.bmj.com/content/bmjopen/3/2/e002276.full.pdf</p> <p>[18] Low intensity ultrasound treatment for acceleration of bone fracture healing - Exogen (TM) bone growth stimulator (2001 Australian Systematic Review) - http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?AccessionNumber=32002000523</p> <p>[19] Long bone fracture: Emerging Treatments https://bestpractice.bmj.com/topics/en-gb/386/emergingtxs</p>		
--	--	--

<h3>3. Impact and Evidence:</h3>
<p>In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.</p>
<p>Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:</p> <p>Age range data is not available for the profile of patients requesting the procedure. A link can however be made between age and both the brittleness of bones and increased vulnerability to breaks from falls etc.</p>

3. Impact and Evidence:	
<p>Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:</p> <p>No specific data is held but it is likely that a greater proportion of patients affected by this decision will have a disability, due both to co- morbidities and the increased likelihood of accidents that result in a broken bone occurring. The potential positive impact of a reduced healing time must be balanced against limited clinical evidence.</p>	
<p>Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:</p> <p>No impact identified</p>	
<p>Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:</p> <p>No impact identified</p>	
<p>Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:</p> <p>No impact identified</p>	
<p>Race: Describe race related impact and evidence. This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:</p> <p>No impact identified</p>	
<p>Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:</p> <p>No impact identified</p>	
<p>Sex: Describe any impact and evidence on men and women. This could include access to services and employment:</p> <p>No impact identified</p>	

3. Impact and Evidence:
<p>Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:</p> <p style="text-align: center;">No impact identified</p>
<p>Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:</p> <p style="text-align: center;">No impact identified</p>
<p>Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)</p> <p style="text-align: center;">No impact identified</p>

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	This condition is not linked to a health inequality.
Is there any impact for groups or communities living in particular geographical areas?	No	No impact identified
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	No impact identified
How will you ensure the proposals reduce health inequalities?		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and while current NICE guidance supports it this is under review. The

		updated guidance will be considered once launched.
Respect – right to have private and family life respected	How will the person’s right to respect for private and family life, confidentiality and consent be upheld?	No evidence of impact from this policy
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person’s right to freedom of thought, conscience and religion?	N/A
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due Regard to this consideration.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to Life	Will or could it affect someone’s right to life? How?	No evidence of impact from this policy
Right to Liberty	Will or could someone be deprived of their liberty? How?	No evidence of impact from this policy

6. Social Value	
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	None
Create fair employment and good work for all	None
Create and develop health and sustainable places and communities	None
Strengthen the role and impact of ill-health prevention	None

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	Protected Characteristic/ Group/ Community	Date

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us So we will):

As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the accessible information standard and the potential need to translate such leaflets into relevant local languages.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have limited impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

None identified

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.

Publication on the CCG’s website.

Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality and Diversity, Senior Manager for Assurance and Compliance or Equality and Human Rights Manager **and** signed-off by a delegated committee

	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		

Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net